

# HOUSE BILL 648

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By: **Delegates Barnes, Frush, Holmes, Hubbard, and Niemann**

Introduced and read first time: February 3, 2010

Assigned to: Environmental Matters

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## A BILL ENTITLED

1 AN ACT concerning

2 **Environment – Drug Stewardship Program**

3 FOR the purpose of requiring a manufacturer of certain drugs, beginning on a certain  
4 date, to operate a drug stewardship program for the collection, transporting,  
5 managing, and disposing of unwanted drugs; requiring a drug stewardship  
6 program to be operated in accordance with certain requirements; requiring a  
7 manufacturer to have Department of the Environment approval of the  
8 manufacturer's proposed program before the manufacturer sells a drug or offers  
9 to sell a drug or operates a program in the State; requiring a manufacturer to  
10 operate a program in a certain manner, pay certain costs, implement the  
11 program without charging a fee at certain times, and accept in the program  
12 certain drugs; requiring a manufacturer or a group of manufacturers to submit  
13 a proposed program to the Department for approval; requiring a proposed  
14 program to include certain information; requiring the Department to review a  
15 proposed program for compliance with certain requirements and take certain  
16 action within a certain number of days; authorizing a manufacturer whose  
17 proposed program has been rejected to take certain actions; prohibiting, with  
18 certain exceptions, a manufacturer from making certain changes to an approved  
19 program; requiring a manufacturer or a group of manufacturers to update and  
20 receive approval of its program at certain intervals; requiring a manufacturer to  
21 promote certain actions with regard to unwanted drugs, establish a toll-free  
22 telephone number and website that provide certain information, and provide  
23 certain materials to certain persons; requiring a manufacturer's program to  
24 provide for the disposal of all unwanted drugs at a certain facility; authorizing a  
25 manufacturer to request the Department's approval to use a certain alternate  
26 disposal technology; authorizing the Department to approve a request under  
27 certain circumstances; requiring a manufacturer that operates an approved  
28 program, on or before certain dates, to submit a report to the Department that  
29 includes certain information; requiring the Department, on or before a certain  
30 date, to establish certain performance standards; authorizing the Department  
31 to require a manufacturer that does not meet the performance standards to

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 make certain modifications with certain approval; authorizing the Department  
 2 to establish fees on manufacturers in a certain amount and deposit the fees in a  
 3 certain Fund; establishing a Drug Stewardship Fund in the Department;  
 4 establishing the purpose, administration, sources, and uses of the Fund;  
 5 requiring the Treasurer to invest the money in the Fund in a certain manner;  
 6 providing that any investment earnings of the Fund shall be retained to the  
 7 credit of the Fund; requiring expenditures from the Fund to be made only in  
 8 accordance with the State budget; requiring the Department to assess certain  
 9 penalties on, send certain warnings to, and take certain actions with regard to a  
 10 manufacturer under certain circumstances; authorizing a manufacturer to take  
 11 certain appeals; requiring certain penalties to be deposited into the Fund;  
 12 requiring the Department to adopt certain regulations; requiring the  
 13 Department to report to the Governor and certain legislative committees on or  
 14 before certain dates; defining certain terms; and generally relating to collection  
 15 and disposal of drugs through a drug stewardship program.

16 BY adding to  
 17 Article – Environment  
 18 Section 7–801 through 7–814 to be under the new subtitle “Subtitle 8. Drug  
 19 Stewardship Program”  
 20 Annotated Code of Maryland  
 21 (2007 Replacement Volume and 2009 Supplement)

22 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
 23 MARYLAND, That the Laws of Maryland read as follows:

24 **Article – Environment**

25 **SUBTITLE 8. DRUG STEWARDSHIP PROGRAM.**

26 **7–801.**

27 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS  
 28 INDICATED.

29 (B) “CONTROLLED HAZARDOUS SUBSTANCE FACILITY” HAS THE  
 30 MEANING STATED IN § 7–201 OF THIS TITLE.

31 (C) “COVERED DRUG” MEANS A DRUG INCLUDED IN A  
 32 MANUFACTURER’S PROGRAM.

33 (D) (1) “DRUG” MEANS:

34 (I) AN ARTICLE RECOGNIZED IN THE UNITED STATES  
 35 PHARMACOPOEIA AND NATIONAL FORMULARY OR THE HOMEOPATHIC

1 PHARMACOPOEIA OF THE UNITED STATES OR ANY SUPPLEMENT OF THOSE  
2 PHARMACOPOEIAS;

3 (II) A SUBSTANCE INTENDED FOR USE IN THE DIAGNOSIS,  
4 CURE, MITIGATION, TREATMENT, OR PREVENTION OF DISEASE IN HUMANS OR  
5 ANIMALS;

6 (III) A SUBSTANCE, OTHER THAN FOOD, INTENDED TO  
7 AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY OF HUMANS OR  
8 ANIMALS; OR

9 (IV) A SUBSTANCE INTENDED FOR USE AS A COMPONENT OF  
10 ANY SUBSTANCES LISTED IN ITEM (I), (II), OR (III) OF THIS PARAGRAPH, BUT  
11 NOT INCLUDING MEDICAL DEVICES OR COMPONENT PARTS OR ACCESSORIES OF  
12 MEDICAL DEVICES.

13 (2) “DRUG” INCLUDES ALL PRESCRIPTION DRUGS,  
14 NONPRESCRIPTION OVER-THE-COUNTER DRUGS, AND VETERINARY DRUGS:

15 (I) IN ANY FORM, INCLUDING PILL, TABLET, CAPSULE,  
16 SUPPOSITORY, LIQUID, CREAM, OINTMENT, LOTION, TRANSDERMAL PATCH,  
17 POWDER, OR AEROSOL FORM; AND

18 (II) INCLUDING BRAND-NAME AND GENERIC DRUGS.

19 (3) “DRUG” DOES NOT INCLUDE VITAMINS OR HERBAL-BASED  
20 REMEDIES.

21 (E) “FUND” MEANS THE DRUG STEWARDSHIP FUND.

22 (F) “MANUFACTURER” MEANS A PERSON OR ENTITY THAT:

23 (1) MANUFACTURES A COVERED DRUG OR HAS LEGAL  
24 OWNERSHIP OF THE BRAND, BRAND NAME, OR CO-BRAND UNDER WHICH A  
25 COVERED DRUG IS SOLD;

26 (2) IMPORTS A COVERED DRUG MANUFACTURED BY A PERSON OR  
27 ENTITY THAT HAS NO PHYSICAL PRESENCE IN THE UNITED STATES; OR

28 (3) SELLS AT WHOLESALE OR RETAIL A COVERED DRUG AND  
29 DOES NOT HAVE LEGAL OWNERSHIP OF THE BRAND OR BRAND NAME BUT  
30 ELECTS TO FULFILL THE MANUFACTURER’S RESPONSIBILITIES FOR THAT  
31 COVERED DRUG.

1           **(G) “PROGRAM” MEANS A DRUG STEWARDSHIP PROGRAM FOR THE**  
2 **COLLECTION, TRANSPORTATION, AND DISPOSAL OF UNWANTED DRUGS.**

3           **(H) “REPORTING PERIOD” MEANS A CALENDAR YEAR.**

4           **(I) (1) “RESIDENTIAL SOURCE” MEANS A SINGLE-FAMILY OR**  
5 **MULTIPLE-FAMILY RESIDENCE OR OTHER LOCATION WHERE INDIVIDUALS OR**  
6 **THEIR PET ANIMALS RESIDE ON A TEMPORARY OR PERMANENT BASIS.**

7           **(2) “RESIDENTIAL SOURCE” INCLUDES A HOSPICE FACILITY, A**  
8 **NURSING HOME, AN ASSISTED LIVING FACILITY, A RESIDENTIAL CHILD CARE**  
9 **PROGRAM, AND A RESIDENTIAL TREATMENT CENTER.**

10           **(3) “RESIDENTIAL SOURCE” DOES NOT INCLUDE A PHARMACY, A**  
11 **RETAIL ESTABLISHMENT, OR ANY OTHER NONRESIDENTIAL SOURCE**  
12 **IDENTIFIED BY THE DEPARTMENT.**

13           **(J) “UNWANTED DRUG” MEANS A COVERED DRUG FROM A RESIDENTIAL**  
14 **SOURCE THAT IS ABANDONED, DISCARDED, OR NO LONGER WANTED BY THE**  
15 **OWNER OF THE COVERED DRUG.**

16 **7-802.**

17           **BEGINNING ON JANUARY 1, 2012, A MANUFACTURER:**

18           **(1) SHALL OPERATE A PROGRAM IN ACCORDANCE WITH THE**  
19 **REQUIREMENTS OF THIS SUBTITLE; AND**

20           **(2) SHALL OBTAIN THE DEPARTMENT’S APPROVAL OF THE**  
21 **MANUFACTURER’S PROPOSED PROGRAM BEFORE THE MANUFACTURER:**

22                   **(I) SELLS A DRUG OR OFFERS A DRUG FOR SALE IN THE**  
23 **STATE; OR**

24                   **(II) OPERATES A PROGRAM IN THE STATE.**

25 **7-803.**

26           **A MANUFACTURER SHALL:**

27           **(1) OPERATE A PROGRAM EITHER INDEPENDENTLY OR JOINTLY**  
28 **WITH OTHER MANUFACTURERS;**

1           **(2) PAY ALL ADMINISTRATIVE AND OPERATIONAL COSTS**  
2 **ASSOCIATED WITH THE PROGRAM, INCLUDING THE COSTS OF:**

3                   **(I) COLLECTING, TRANSPORTING, MANAGING, AND**  
4 **DISPOSING OF UNWANTED DRUGS; AND**

5                   **(II) RECYCLING OR DISPOSING OF THE PACKAGING**  
6 **RELATED TO THE UNWANTED DRUGS;**

7           **(3) IMPLEMENT THE PROGRAM WITHOUT CHARGING A FEE AT**  
8 **THE TIME OF THE SALE OF COVERED DRUGS OR AT THE TIME UNWANTED DRUGS**  
9 **ARE DELIVERED OR COLLECTED FOR DISPOSAL;**

10           **(4) OPERATE THE PROGRAM:**

11                   **(I) AS APPROVED BY THE DEPARTMENT; AND**

12                   **(II) IN ACCORDANCE WITH THE REQUIREMENTS OF THIS**  
13 **SUBTITLE AND OTHER APPLICABLE STATE AND FEDERAL LAWS; AND**

14           **(5) ACCEPT IN THE PROGRAM COVERED DRUGS FROM ANY**  
15 **MANUFACTURER.**

16 **7-804.**

17           **(A) A MANUFACTURER, OR A GROUP OF MANUFACTURERS SEEKING TO**  
18 **OPERATE A JOINT PROGRAM, SHALL SUBMIT A PROPOSED PROGRAM TO THE**  
19 **DEPARTMENT FOR APPROVAL BEFORE THE PROGRAM MAY OPERATE.**

20           **(B) A PROPOSED PROGRAM SHALL INCLUDE:**

21                   **(1) THE NAME OF AND CONTACT INFORMATION FOR EACH**  
22 **MANUFACTURER PARTICIPATING IN THE PROGRAM;**

23                   **(2) (I) PROGRAM PERFORMANCE GOALS, INCLUDING**  
24 **RECOVERY GOALS FOR THE FIRST, SECOND, AND THIRD YEARS OF THE**  
25 **PROGRAM, EXPRESSED AS POUNDS OF UNWANTED DRUGS DISPOSED OF PER**  
26 **CAPITA; AND**

27                   **(II) AN EXPLANATION OF HOW THE RECOVERY GOALS HAVE**  
28 **BEEN SET TO RECOVER A SIGNIFICANT PERCENTAGE OF UNWANTED DRUGS,**  
29 **RELATIVE TO THE QUANTITY OF UNWANTED DRUGS THAT MAY BE AVAILABLE**  
30 **FOR DISPOSAL;**



1           **(2) APPEAL AS PROVIDED UNDER TITLE 10, SUBTITLE 2 OF THE**  
2 **STATE GOVERNMENT ARTICLE.**

3           **(D) (1) EXCEPT AS PROVIDED IN PARAGRAPHS (2) AND (3) OF THIS**  
4 **SUBSECTION, A MANUFACTURER MAY NOT MAKE SUBSTANTIVE CHANGES TO AN**  
5 **APPROVED PROGRAM WITHOUT WRITTEN APPROVAL FROM THE DEPARTMENT.**

6           **(2) A MANUFACTURER MAY ALTER THE LIST OF CONTROLLED**  
7 **HAZARDOUS SUBSTANCE FACILITIES AND OTHER ENTITIES UNDER CONTRACT**  
8 **FOR DRUG COLLECTION OR DISPOSAL WITHOUT RECEIVING WRITTEN**  
9 **APPROVAL FROM THE DEPARTMENT IF:**

10           **(I) THE MANUFACTURER INFORMS THE DEPARTMENT OF**  
11 **THE ALTERATION AT LEAST 15 DAYS BEFORE ITS EFFECTIVE DATE; AND**

12           **(II) THE DEPARTMENT DOES NOT REJECT THE ALTERATION**  
13 **BEFORE THE EFFECTIVE DATE.**

14           **(3) AN ADDITIONAL MANUFACTURER MAY PARTICIPATE IN AN**  
15 **APPROVED PROGRAM WITHOUT RECEIVING WRITTEN APPROVAL FROM THE**  
16 **DEPARTMENT IF THE MANUFACTURER RESPONSIBLE FOR IMPLEMENTING THE**  
17 **PROGRAM PROVIDES THE DEPARTMENT WITH AN UPDATED MANUFACTURER**  
18 **PARTICIPANT LIST WITHIN 15 DAYS AFTER AN ADDITIONAL MANUFACTURER**  
19 **BEGINS PARTICIPATION IN THE PROGRAM.**

20           **(E) AT LEAST EVERY 4 YEARS, A MANUFACTURER, OR A GROUP OF**  
21 **MANUFACTURERS FOR A JOINT PROGRAM, SHALL UPDATE THE**  
22 **MANUFACTURER'S PROGRAM AND SUBMIT THE PROGRAM TO THE DEPARTMENT**  
23 **FOR APPROVAL.**

24 **7-806.**

25           **A MANUFACTURER SHALL:**

26           **(1) PROMOTE THE USE OF A PROGRAM AND THE PROPER**  
27 **DISPOSAL OF UNWANTED DRUGS SO THAT COLLECTION OPTIONS ARE WIDELY**  
28 **UNDERSTOOD BY CUSTOMERS, PHARMACISTS, RETAILERS OF COVERED DRUGS,**  
29 **AND HEALTH CARE PRACTITIONERS;**

30           **(2) ESTABLISH A TOLL-FREE TELEPHONE NUMBER AND**  
31 **PUBLICLY ACCESSIBLE WEBSITE THAT PROVIDE INFORMATION ABOUT**  
32 **COLLECTION OPTIONS; AND**

1           **(3) PROVIDE TO PHARMACIES, HEALTH CARE FACILITIES, AND**  
2 **OTHER INTERESTED PARTIES AT NO COST:**

3                   **(I) EDUCATIONAL AND OUTREACH MATERIALS DESCRIBING**  
4 **WHERE AND HOW TO RETURN UNWANTED DRUGS; AND**

5                   **(II) PREPAID MAILING ENVELOPES ADDRESSED TO THE**  
6 **ENTITY DESIGNATED BY THE MANUFACTURER TO COLLECT UNWANTED DRUGS**  
7 **FOR THE RETURN OF UNWANTED DRUGS.**

8 **7-807.**

9           **(A) A MANUFACTURER'S PROGRAM SHALL PROVIDE FOR THE DISPOSAL**  
10 **OF ALL UNWANTED DRUGS AT A CONTROLLED HAZARDOUS SUBSTANCE**  
11 **FACILITY.**

12           **(B) A MANUFACTURER MAY REQUEST THE DEPARTMENT'S APPROVAL**  
13 **TO USE AN ALTERNATE DISPOSAL TECHNOLOGY THAT PROVIDES**  
14 **ENVIRONMENTAL AND HUMAN HEALTH PROTECTION SUPERIOR TO THE**  
15 **ENVIRONMENTAL AND HUMAN HEALTH PROTECTION PROVIDED BY CURRENT**  
16 **HAZARDOUS WASTE DISPOSAL TECHNOLOGIES.**

17           **(C) THE DEPARTMENT MAY APPROVE A REQUEST SUBMITTED UNDER**  
18 **SUBSECTION (B) OF THIS SECTION IF THE DEPARTMENT FINDS:**

19                   **(1) THE REQUESTED DISPOSAL TECHNOLOGY IS PROVEN AND**  
20 **AVAILABLE; AND**

21                   **(2) THE REQUESTED DISPOSAL TECHNOLOGY PROVIDES**  
22 **EQUIVALENT PROTECTION IN EACH, AND SUPERIOR PROTECTION IN ONE OR**  
23 **MORE, OF THE FOLLOWING AREAS:**

24                           **(I) MONITORING OF ANY EMISSIONS OR WASTE;**

25                           **(II) WORKER HEALTH AND SAFETY;**

26                           **(III) AIR, WATER, OR LAND EMISSIONS CONTRIBUTING TO**  
27 **PERSISTENT, BIOACCUMULATIVE, AND TOXIC POLLUTION; AND**

28                           **(IV) OVERALL ENVIRONMENT AND HUMAN HEALTH.**

29 **7-808.**

1           (A) ON OR BEFORE FEBRUARY 1, 2013, AND ON OR BEFORE EACH  
2 FEBRUARY 1 THEREAFTER, A MANUFACTURER THAT OPERATES AN APPROVED  
3 PROGRAM SHALL SUBMIT A REPORT TO THE DEPARTMENT, IN A FORMAT  
4 REQUIRED BY THE DEPARTMENT, COVERING THE PREVIOUS REPORTING  
5 PERIOD.

6           (B) THE REPORT SHALL INCLUDE:

7                   (1) A LIST OF MANUFACTURERS PARTICIPATING IN THE  
8 PROGRAM;

9                   (2) THE AMOUNT, BY WEIGHT, OF UNWANTED DRUGS COLLECTED;

10                   (3) DOCUMENTATION VERIFYING COLLECTION AND DISPOSAL OF  
11 THE UNWANTED DRUGS;

12                   (4) THE CONTROLLED HAZARDOUS SUBSTANCE FACILITIES USED,  
13 THE LOCATION OF THOSE FACILITIES, AND THE WEIGHT OF UNWANTED DRUGS  
14 COLLECTED AND DISPOSED OF AT EACH FACILITY;

15                   (5) DOCUMENTATION OF COMPLIANCE WITH POLICIES AND  
16 PROCEDURES OF THE APPROVED PROGRAM FOR COLLECTING, TRANSPORTING,  
17 AND DISPOSING OF UNWANTED DRUGS;

18                   (6) WHETHER ANY SAFETY OR SECURITY PROBLEMS OCCURRED  
19 DURING COLLECTION, TRANSPORTATION, OR DISPOSAL OF UNWANTED DRUGS  
20 AND, IF PROBLEMS OCCURRED, WHAT CHANGES ARE PROPOSED FOR POLICIES,  
21 PROCEDURES, OR TRACKING MECHANISMS TO IMPROVE SAFETY AND SECURITY;

22                   (7) A DESCRIPTION OF THE PUBLIC EDUCATION EFFORT AND  
23 COMMUNICATION STRATEGY IMPLEMENTED DURING THE REPORTING PERIOD;

24                   (8) A DESCRIPTION OF ANY KNOWN RESEARCH REGARDING  
25 DISPOSAL TECHNIQUES THAT PROVIDE SUPERIOR PROTECTION TO HUMAN  
26 HEALTH AND THE ENVIRONMENT BEYOND THE PROTECTION PROVIDED BY  
27 CURRENT HAZARDOUS WASTE DISPOSAL TECHNIQUES;

28                   (9) HOW THE PROGRAM MET THE PERFORMANCE GOALS  
29 ESTABLISHED IN THE PROGRAM AND, IF THE PROGRAM DID NOT MEET THE  
30 PERFORMANCE GOALS, WHAT ACTIONS THE MANUFACTURER WILL TAKE TO  
31 MEET THE PERFORMANCE GOALS; AND

32                   (10) ANY OTHER INFORMATION THAT THE DEPARTMENT  
33 REASONABLY MAY REQUIRE.

1 **7-809.**

2 (A) ON OR BEFORE JANUARY 1, 2014, THE DEPARTMENT SHALL  
3 ESTABLISH MANDATED PERFORMANCE STANDARDS, INCLUDING RECOVERY  
4 RATES, FOR THE FOURTH AND SUBSEQUENT YEARS OF A MANUFACTURER'S  
5 PROGRAM.

6 (B) THE DEPARTMENT MAY REQUIRE A MANUFACTURER THAT DOES  
7 NOT MEET THE MANDATED PERFORMANCE STANDARDS TO MODIFY THE  
8 MANUFACTURER'S PROGRAM TO MEET THE STANDARDS.

9 (C) THE DEPARTMENT SHALL APPROVE A MANUFACTURER'S PROGRAM  
10 MODIFICATIONS BEFORE THE MODIFICATIONS MAY BE IMPLEMENTED.

11 **7-810.**

12 (A) THE DEPARTMENT MAY ESTABLISH FEES ON MANUFACTURERS IN  
13 AN AMOUNT SUFFICIENT TO COVER THE COST OF CARRYING OUT THE  
14 RESPONSIBILITIES OF THE DEPARTMENT UNDER THIS SUBTITLE.

15 (B) ALL FEES COLLECTED SHALL BE DEPOSITED IN THE FUND  
16 ESTABLISHED UNDER § 7-811 OF THIS SUBTITLE.

17 **7-811.**

18 (A) THERE IS A DRUG STEWARDSHIP FUND IN THE DEPARTMENT.

19 (B) THE PURPOSE OF THE FUND IS TO COVER THE COST OF CARRYING  
20 OUT THE RESPONSIBILITIES OF THE DEPARTMENT UNDER THIS SUBTITLE.

21 (C) THE DEPARTMENT SHALL ADMINISTER THE FUND.

22 (D) (1) THE FUND IS A SPECIAL, NONLAPSING FUND THAT IS NOT  
23 SUBJECT TO § 7-302 OF THE STATE FINANCE AND PROCUREMENT ARTICLE.

24 (2) THE STATE TREASURER SHALL HOLD THE FUND  
25 SEPARATELY, AND THE COMPTROLLER SHALL ACCOUNT FOR THE FUND.

26 (E) THE FUND CONSISTS OF:

27 (1) REVENUE DISTRIBUTED TO THE FUND UNDER § 7-810 OF  
28 THIS SUBTITLE;

1           **(2) REVENUE COLLECTED FROM PENALTIES UNDER § 7-812 OF**  
2 **THIS SUBTITLE;**

3           **(3) MONEY APPROPRIATED IN THE STATE BUDGET TO THE FUND;**

4           **(4) INVESTMENT EARNINGS; AND**

5           **(5) ANY OTHER MONEY FROM ANY OTHER SOURCE ACCEPTED**  
6 **FOR THE BENEFIT OF THE FUND.**

7           **(F) THE FUND MAY BE USED ONLY FOR THE DEPARTMENT'S COST IN**  
8 **CARRYING OUT ITS RESPONSIBILITIES UNDER THIS SUBTITLE.**

9           **(G) (1) THE STATE TREASURER SHALL INVEST THE MONEY OF THE**  
10 **FUND IN THE SAME MANNER AS OTHER STATE MONEY MAY BE INVESTED.**

11           **(2) ANY INVESTMENT EARNINGS OF THE FUND SHALL BE PAID**  
12 **INTO THE FUND.**

13           **(H) EXPENDITURES FROM THE FUND MAY BE MADE ONLY IN**  
14 **ACCORDANCE WITH THE STATE BUDGET.**

15 **7-812.**

16           **(A) BEGINNING ON JANUARY 1, 2012, THE DEPARTMENT SHALL SEND A**  
17 **WRITTEN WARNING TO A MANUFACTURER WITHOUT AN APPROVED PROGRAM**  
18 **THAT SELLS A DRUG OR OFFERS A DRUG FOR SALE IN THE STATE.**

19           **(B) IF A MANUFACTURER DOES NOT HAVE AN APPROVED PROGRAM AND**  
20 **CONTINUES TO SELL A DRUG OR OFFER A DRUG FOR SALE IN THE STATE 60 OR**  
21 **MORE DAYS AFTER RECEIVING A WRITTEN WARNING, THE DEPARTMENT SHALL**  
22 **ASSESS A PENALTY OF \$10,000 FOR EACH DAY THAT THE VIOLATION**  
23 **CONTINUES.**

24           **(C) IF THE DEPARTMENT FINDS THE MANUFACTURER OUT OF**  
25 **COMPLIANCE WITH THE REQUIREMENTS OF THIS SUBTITLE, THE DEPARTMENT**  
26 **SHALL:**

27           **(1) FIRST SEND A WRITTEN WARNING TO THE MANUFACTURER**  
28 **THAT AFFORDS THE MANUFACTURER 30 DAYS TO CORRECT THE**  
29 **NONCOMPLIANCE; AND**

30           **(2) AFTER 30 DAYS OF NONCOMPLIANCE BY THE**  
31 **MANUFACTURER, ASSESS A PENALTY OF \$5,000 FOR THE FIRST VIOLATION AND**

1 **\$10,000 FOR THE SECOND AND EACH SUBSEQUENT 30-DAY PERIOD OF**  
2 **NONCOMPLIANCE.**

3 **(D) NOTWITHSTANDING SUBSECTION (C) OF THIS SECTION, IF THE**  
4 **DEPARTMENT DETERMINES THAT IT IS NECESSARY TO PROTECT THE PUBLIC**  
5 **FROM IMMINENT DANGER, THE DEPARTMENT MAY IMMEDIATELY AMEND,**  
6 **SUSPEND, OR CANCEL AN APPROVED PROGRAM WITHOUT SENDING A WRITTEN**  
7 **WARNING.**

8 **(E) A MANUFACTURER MAY APPEAL PENALTIES AND OTHER ACTIONS**  
9 **IMPOSED UNDER THIS SECTION AS PROVIDED UNDER TITLE 10, SUBTITLE 2 OF**  
10 **THE STATE GOVERNMENT ARTICLE.**

11 **(F) ALL PENALTIES IMPOSED UNDER THIS SECTION SHALL BE**  
12 **DEPOSITED INTO THE FUND.**

13 **7-813.**

14 **THE DEPARTMENT SHALL ADOPT REGULATIONS TO IMPLEMENT THIS**  
15 **SUBTITLE.**

16 **7-814.**

17 **ON OR BEFORE JANUARY 1, 2012, AND EACH JANUARY 1 THEREAFTER,**  
18 **THE DEPARTMENT SHALL REPORT TO THE GOVERNOR AND, IN ACCORDANCE**  
19 **WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, THE SENATE**  
20 **EDUCATION, HEALTH, AND ENVIRONMENTAL AFFAIRS COMMITTEE AND THE**  
21 **HOUSE ENVIRONMENTAL MATTERS COMMITTEE ON THE IMPLEMENTATION OF**  
22 **THIS SUBTITLE.**

23 **SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect**  
24 **October 1, 2010.**